

APPLICANT(S): DALTON, James T. et al.

SERIAL NO.: 10/849,039

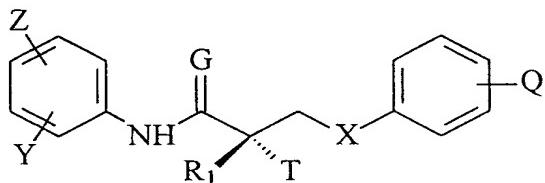
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AMENDMENTS TO THE CLAIMS

Please add or amend the claims to read as follows, and cancel without prejudice or disclaimer to resubmission in a divisional or continuation application claims indicated as cancelled:

1. (*Currently Amended*) A metabolite of a selective androgen receptor modulator (SARM) compound, wherein said SARM is represented by the structure of formula I:



I

wherein G is O or S;

X is O;

T is OH, OR, -NHC₂H₃, or NHCOR;

Z is NO₂, CN, COOH, COR, NHCOR or CONHR;

Y is CF₃, F, I, Br, Cl, CN, C(R)₃ or Sn(R)₃;

Q is acetamido or trifluoroacetamido;

R is alkyl, haloalkyl, dihaloalkyl, trihaloalkyl, CH₂F, CHF₂, CF₃, CF₂CF₃, aryl, phenyl, F, Cl, Br, I, alkenyl or OH; and

R1 is CH₃, CH₂F, CHF₂, CF₃, CH₂CH₃, or CF₂CF₃; and

wherein said metabolite is an hydroxylated, deacetylated, hydrolyzed, methylated or aminated derivative of compound of formula (I).

2. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein G is O.

3. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein T is OH.

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4. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein R1 is CH₃.

5. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein Z is CN.

6. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein Y is CF₃.

7. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein Q is in the para position.

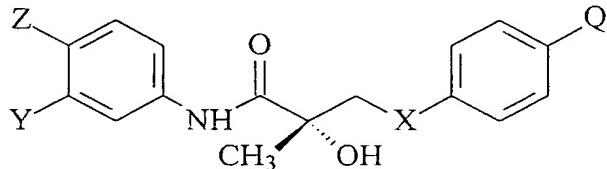
8. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein Z is in the para position.

9. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein Y is in the meta position.

10. (*Cancelled*)

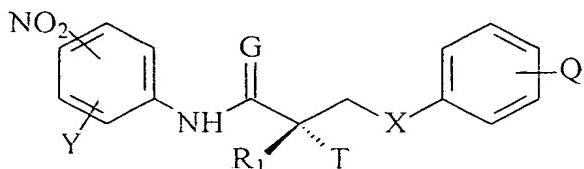
11. (*Cancelled*)

12. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 1, wherein said SARM is represented by the structure of formula II:



II

13. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 1, wherein said SARM is represented by the structure of formula VII:



VII

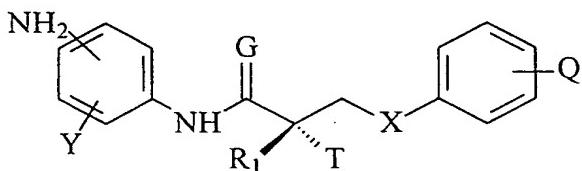
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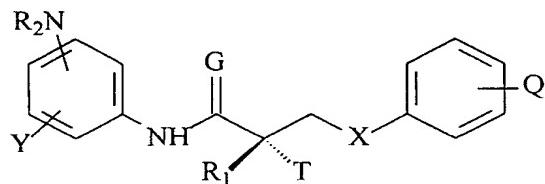
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14. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 13, wherein said metabolite is represented by the structure:

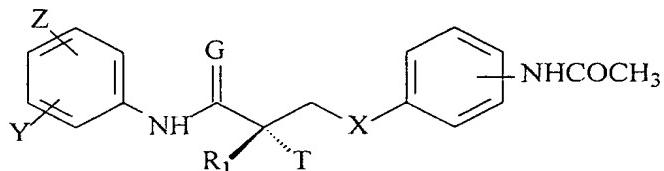


15. (*Original*) The selective androgen receptor modulator metabolite of claim 13, wherein said metabolite is represented by the structure:



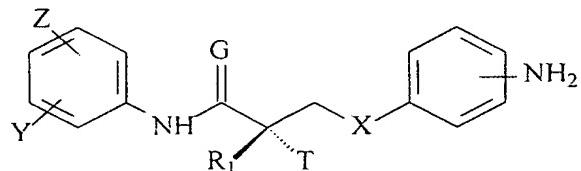
wherein NR₂ is NO, NHOH, NHOSO₃, or NHO-glucoronide.

16. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein said SARM is represented by the structure of formula VIII:



VIII

17. (*Original*) The selective androgen receptor modulator metabolite of claim 16, wherein said metabolite is represented by the structure:



18. (*Original*) The selective androgen receptor modulator metabolite of claim 1, wherein said metabolite is a hydroxylated derivative of the SARM compound of formula I.

19. (*Original*) The selective androgen receptor modulator metabolite of claim 18,

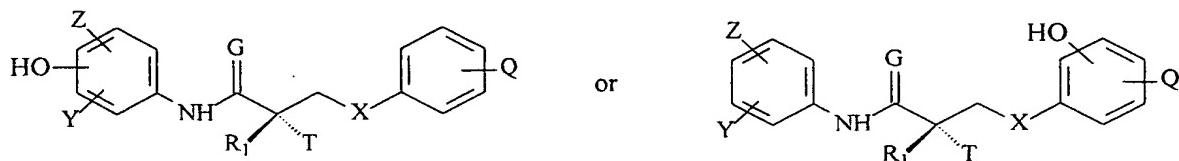
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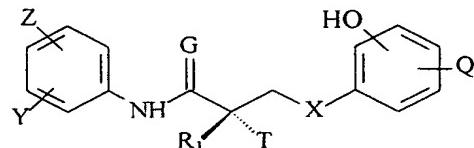
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wherein said metabolite is represented by the structure:

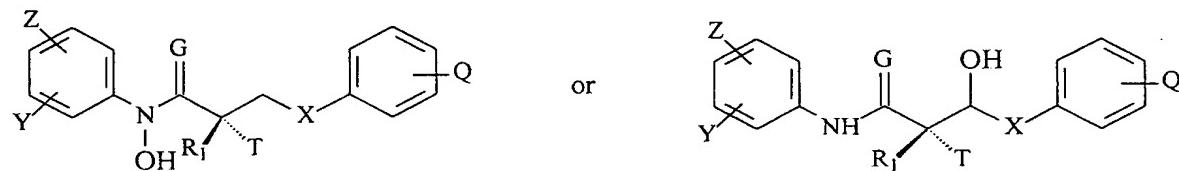


or

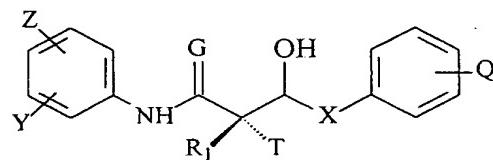


20. (Original) The selective androgen receptor modulator metabolite of claim 18,

wherein said metabolite is represented by the structure:

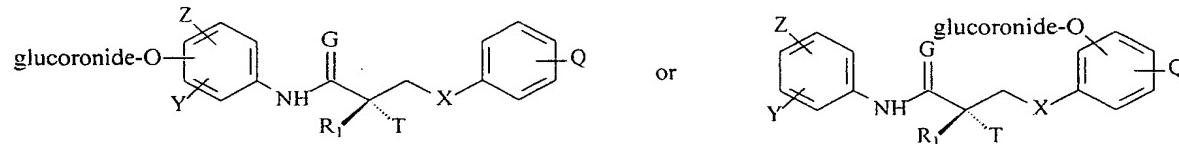


or

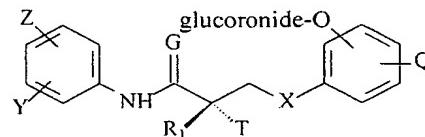


21. (Withdrawn) The selective androgen receptor modulator metabolite of claim 1,
wherein said metabolite is an O-glucoronide derivative of the SARM compound of
formula I.

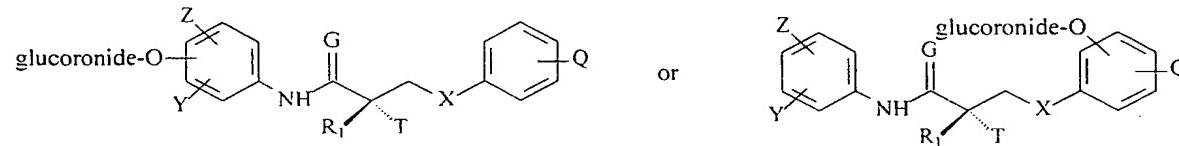
22. (Withdrawn) The selective androgen receptor modulator metabolite of claim 21,
wherein said metabolite is represented by the structure:



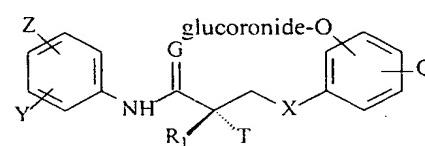
or



23. (Withdrawn) The selective androgen receptor modulator metabolite of claim 21,
wherein said metabolite is represented by the structure:



or



24. (Cancelled)

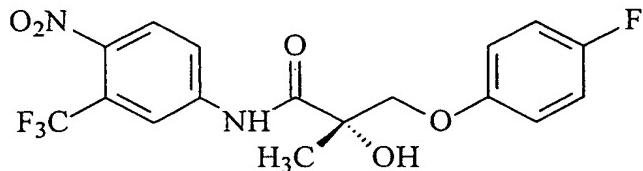
25. (Previously Presented) The selective androgen receptor modulator metabolite of
claim 1, wherein said SARM is represented by the structure of formula III:

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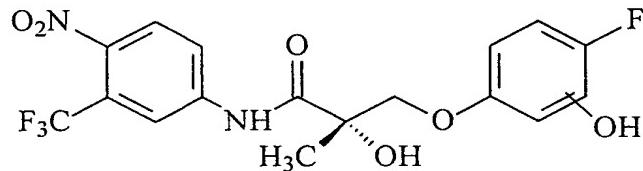
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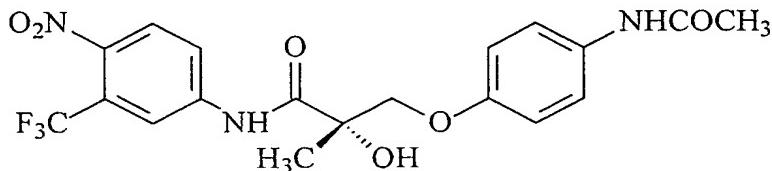


III

26. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 25, wherein said metabolite is represented by the structure:

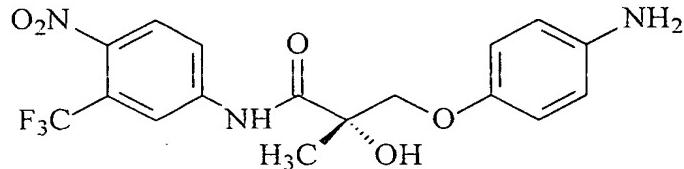


27. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 1, wherein said SARM is represented by the structure of formula IV:



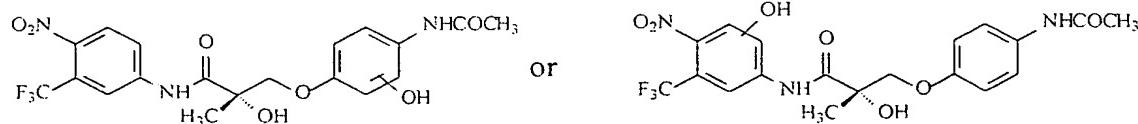
IV

28. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 27, wherein said metabolite is represented by the structure:



29. (*Original*) The selective androgen receptor modulator metabolite of claim 27, wherein said metabolite is a hydroxylated derivative of the SARM compound of formula IV.

30. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 29, wherein said metabolite is represented by the structure:



31. (*Currently Amended*) The selective androgen receptor modulator metabolite of

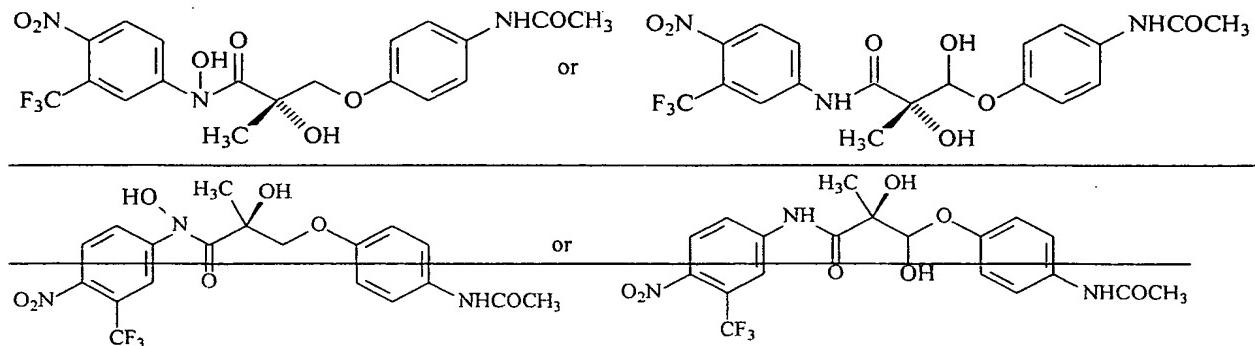
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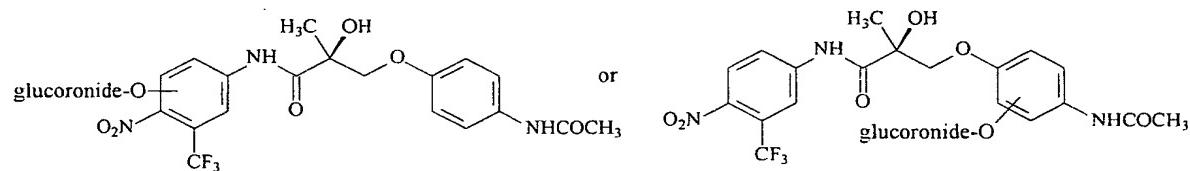
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claim 29, wherein said metabolite is represented by the structure:

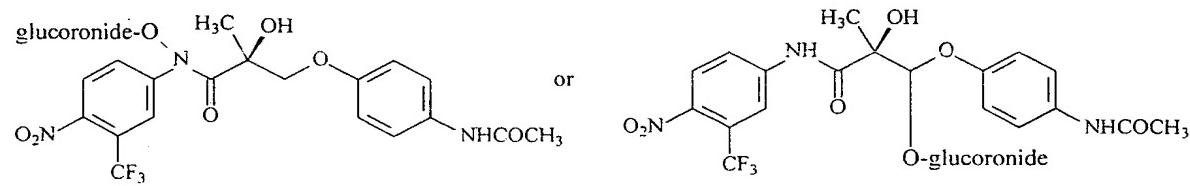


32. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 27, wherein said metabolite is an O-glucuronide derivative of the SARM compound of formula I.

33. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 32, wherein said metabolite is represented by the structure:



34. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 32, wherein said metabolite is represented by the structure:



35. (*Cancelled*)

36. (*Original*) A composition comprising the selective androgen receptor modulator metabolite of claim 1; and a suitable carrier or diluent.

37. (*Original*) A pharmaceutical composition comprising an effective amount of the selective androgen receptor modulator metabolite of claim 1; and a pharmaceutically acceptable carrier or diluent.

38. (*Withdrawn*) A method of binding a selective androgen receptor modulator

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compound to an androgen receptor, comprising the step of contacting the androgen receptor with the selective androgen receptor modulator metabolite of claim 1, in an amount effective to bind the selective androgen receptor modulator metabolite to the androgen receptor.

39. (*Withdrawn*) A method of suppressing spermatogenesis in a subject comprising contacting an androgen receptor of the subject with the selective androgen receptor modulator metabolite of claim 1, in an amount effective to suppress sperm production.

40. (*Withdrawn*) A method of contraception in a male subject, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to suppress sperm production in said subject, thereby effecting contraception in said subject.

41. (*Withdrawn*) A method of hormone therapy comprising the step of contacting an androgen receptor of a subject with the selective androgen receptor modulator metabolite of claim 1, in an amount effective to effect a change in an androgen-dependent condition.

42. (*Withdrawn*) A method of hormone replacement therapy comprising the step of contacting an androgen receptor of a subject with the selective androgen receptor modulator metabolite of claim 1, in an amount effective to effect a change in an androgen-dependent condition.

43. (*Withdrawn*) A method of treating a subject having a hormone related condition, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to effect a change in an androgen-dependent condition.

44. (*Withdrawn*) A method of treating a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to treat prostate cancer in said subject.

45. (*Withdrawn*) A method of preventing prostate cancer in a subject, comprising the step of administering to said subject the selective androgen receptor modulator product of claim 1, in an amount effective to prevent prostate cancer in said subject.

46. (*Withdrawn*) A method of delaying the progression of prostate cancer in a subject suffering from prostate cancer, comprising the step of administering to said subject

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the selective androgen receptor modulator metabolite of claim 1, in an amount effective to delay the progression of prostate cancer in said subject.

47. (*Withdrawn*) A method of preventing the recurrence of prostate cancer in a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to prevent the recurrence of prostate cancer in said subject.

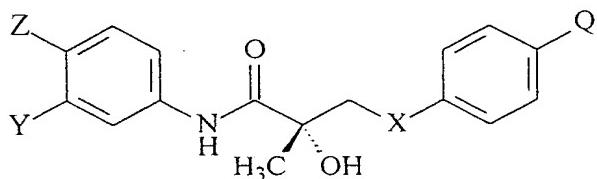
48. (*Withdrawn*) A method of treating the recurrence of prostate cancer in a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to treat the recurrence of prostate cancer in said subject.

49. (*Withdrawn*) A method of treating a dry eye condition in a subject suffering from dry eyes, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to treat dry eyes in said subject.

50. (*Withdrawn*) A method of preventing a dry eye condition in a subject, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 1, in an amount effective to prevent dry eyes in said subject.

51. (*Withdrawn*) A method of inducing apoptosis in a cancer cell, comprising the step of contacting said cell with the selective androgen receptor modulator metabolite of claim 1, in an amount effective to induce apoptosis in said cancer cell.

52. (*Currently Amended*) A metabolite of a selective androgen receptor modulator (SARM) compound, wherein said SARM compound is represented by the structure of formula II:



II

wherein X is O;

Z is NO₂, CN, COOH, COR, NHCOR or CONHR;

Y is CF₃, F, I, Br, Cl, CN, C(R)₃ or Sn(R)₃;

Q is acetamido or trifluoroacetamido;

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R is alkyl, haloalkyl, dihaloalkyl, trihaloalkyl, CH₂F, CHF₂, CF₃, CF₂CF₃, aryl, phenyl, F, Cl, Br, I, alkenyl or OH; and

R₁ is CH₃, CH₂F, CHF₂, CF₃, CH₂CH₃, or CF₂CF₃; and

wherein said metabolite is an hydroxylated, deacetylated, methylated—or aminated derivative of compound of formula (II). (*Original*) The selective androgen receptor modulator metabolite of claim 52, wherein Z is CN.

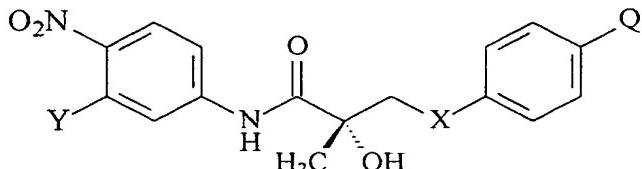
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53. (*Original*) The selective androgen receptor modulator metabolite of claim 52, wherein Y is CF₃.

54. (*Original*) The selective androgen receptor modulator metabolite of claim 52, wherein said compound is an androgen receptor agonist.

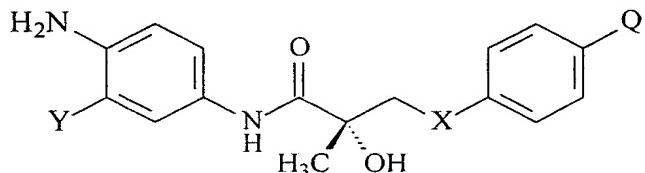
55. (*Original*) The selective androgen receptor modulator metabolite of claim 52, wherein said compound is an androgen receptor antagonist.

56. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 52, wherein said SARM is represented by the structure of formula IX:

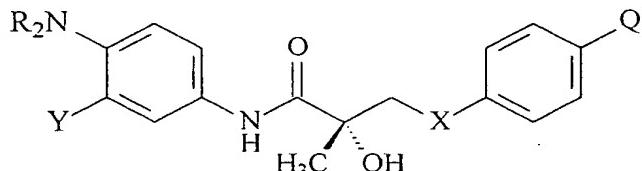


IX

57. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 57, wherein said metabolite is represented by the structure:



58. (*Currently amended*) The selective androgen receptor modulator metabolite of claim 57, wherein said metabolite is represented by the structure:



wherein N(R)₂ is NHOH, NO, NHOSO₃, or NHO-glucoronide.

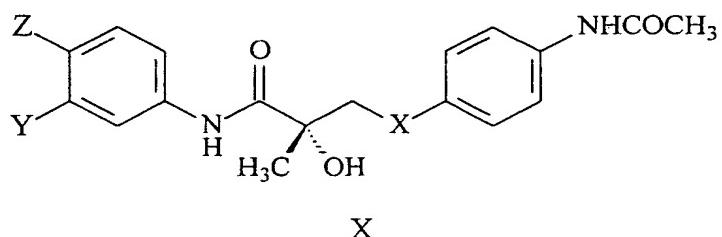
59. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 52, wherein said SARM is represented by the structure of formula X:

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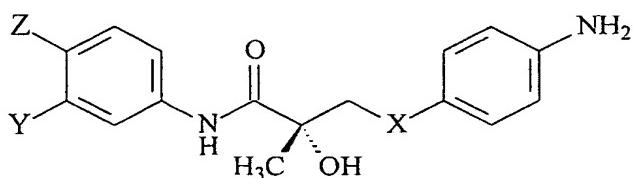
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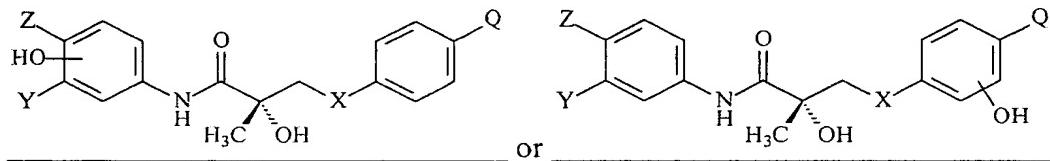


60. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 60, wherein said metabolite is represented by the structure:

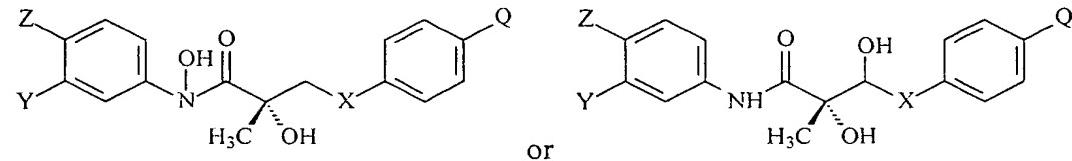


61. (*Original*) The selective androgen receptor modulator metabolite of claim 52, wherein said metabolite is a hydroxylated derivative of the SARM compound of formula II.

62. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 62, wherein said metabolite is represented by the structure:



63. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 62, wherein said metabolite is represented by the structure:



64. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 52, wherein said metabolite is an O-glucuronide derivative of the SARM compound of formula II.

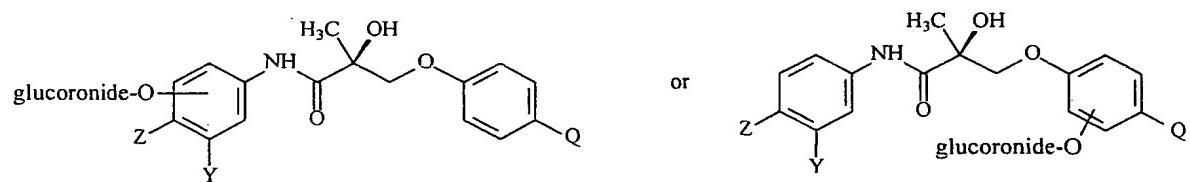
65. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 65, wherein said metabolite is represented by the structure:

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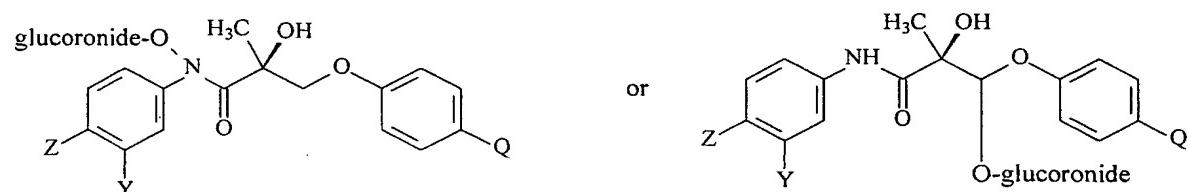
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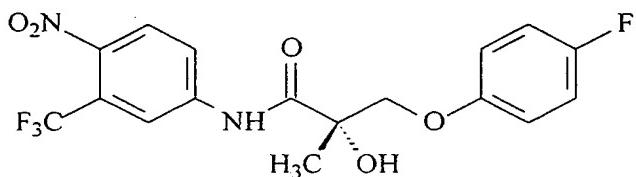


66. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 65, wherein said metabolite is represented by the structure:



67. (*Cancelled*)

68. (*Currently Amended*) A metabolite of a selective androgen receptor modulator (SARM) compound, wherein said SARM compound is represented by the structure of formula III:



III

wherein said metabolite is an hydroxylated, deacetylated, methylated or aminated derivative of compound of formula (II).

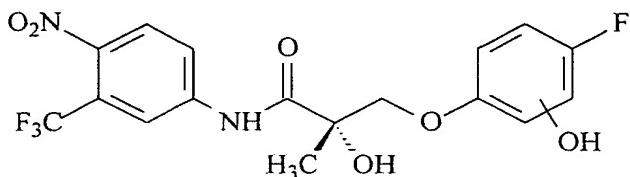
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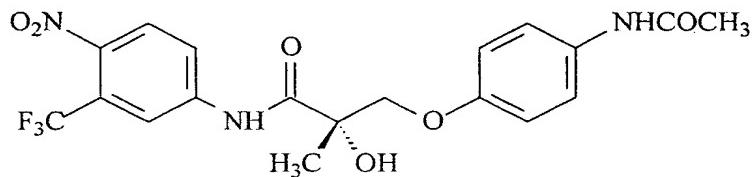
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69. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 69, wherein said metabolite is represented by the structure:

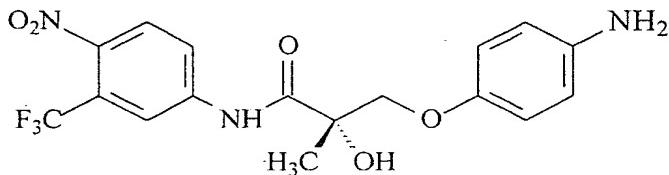


70. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 52, wherein said SARM is represented by the structure of formula IV:



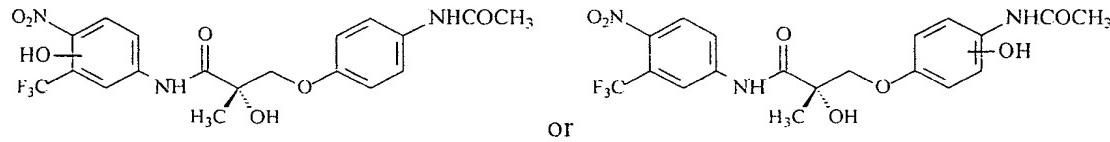
IV

71. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 71, wherein said metabolite is represented by the structure:



72. (*Original*) The selective androgen receptor modulator metabolite of claim 71, wherein said metabolite is a hydroxylated derivative of the SARM compound of formula IV.

73. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 73, wherein said SARM metabolite is represented by the structure:



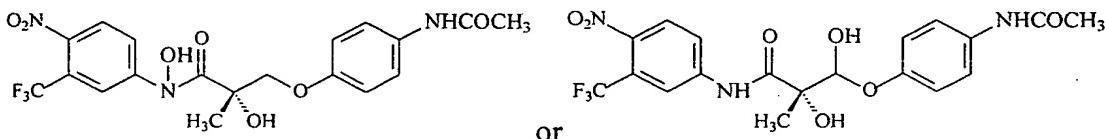
74. (*Previously Presented*) The selective androgen receptor modulator metabolite of claim 73, wherein said metabolite is represented by the structure:

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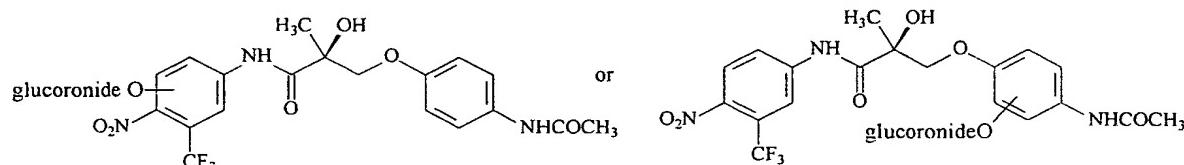
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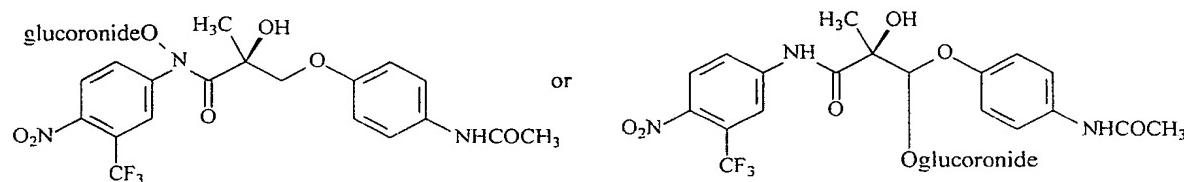


75. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 71, wherein said metabolite is an O-glucoronide derivative of the SARM compound of formula IV.

76. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 76, wherein said metabolite is represented by the structure:



77. (*Withdrawn*) The selective androgen receptor modulator metabolite of claim 76, wherein said metabolite is represented by the structure:



78. (*Cancelled*)

79. (*Original*) A composition comprising the selective androgen receptor modulator metabolite of claim 52; and a suitable carrier or diluent.

80. (*Original*) A pharmaceutical composition comprising an effective amount of the selective androgen receptor modulator metabolite of claim 52; and a pharmaceutically acceptable carrier or diluent.

81. (*Withdrawn*) A method of binding a selective androgen receptor modulator compound to an androgen receptor, comprising the step of contacting the androgen receptor with the selective androgen receptor modulator metabolite of claim 52, in an amount effective to bind the selective androgen receptor modulator metabolite to the androgen receptor.

82. (*Withdrawn*) A method of suppressing spermatogenesis in a subject comprising contacting an androgen receptor of the subject with the selective androgen receptor

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modulator metabolite of claim 52, in an amount effective to suppress sperm production.

83. (*Withdrawn*) A method of contraception in a male subject, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an amount effective to suppress sperm production in said subject, thereby effecting contraception in said subject.

84. (*Withdrawn*) A method of hormone therapy comprising the step of contacting an androgen receptor of a subject with the selective androgen receptor modulator metabolite of claim 52, in an amount effective to effect a change in an androgen-dependent condition.

85. (*Withdrawn*) A method of hormone replacement therapy comprising the step of contacting an androgen receptor of a subject with the selective androgen receptor modulator metabolite of claim 52, in an amount effective to effect a change in an androgen-dependent condition.

86. (*Withdrawn*) A method of treating a subject having a hormone related condition, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an amount effective to effect a change in an androgen-dependent condition.

87. (*Withdrawn*) A method of treating a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an amount effective to treat prostate cancer in said subject.

88. (*Withdrawn*) A method of preventing prostate cancer in a subject, comprising the step of administering to said subject the selective androgen receptor modulator produg of claim 52, in an amount effective to prevent prostate cancer in said subject.

89. (*Withdrawn*) A method of delaying the progression of prostate cancer in a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 32, in an amount effective to delay the progression of prostate cancer in said subject.

90. (*Withdrawn*) A method of preventing the recurrence of prostate cancer in a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an

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amount effective to prevent the recurrence of prostate cancer in said subject.

91. (*Withdrawn*) A method of treating the recurrence of prostate cancer in a subject suffering from prostate cancer, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an amount effective to treat the recurrence of prostate cancer in said subject.

92. (*Withdrawn*) A method of treating a dry eye condition in a subject suffering from dry eyes, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an amount effective to treat dry eyes in said subject.

93. (*Withdrawn*) A method of preventing a dry eye condition in a subject, comprising the step of administering to said subject the selective androgen receptor modulator metabolite of claim 52, in an amount effective to prevent dry eyes in said subject.

94. (*Withdrawn*) A method of inducing apoptosis in a cancer cell, comprising the step of contacting said cell with the selective androgen receptor modulator metabolite of claim 52, in an amount effective to induce apoptosis in said cancer cell.